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PATENT  
Attorney Docket No. 207324

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

ALAM et al.

Application No. 10/034,432

Filed: December 27, 2001

For: INDOCYANINE GREEN (ICG)  
COMPOSITIONS AND RELATED  
METHODS OF USE

Group Art Unit:

Examiner:

03 CD  
L. Park  
7-23-02  
#4/IDS

### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- ☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

#### Copies of the References

- ☐ Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☒ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status ( <i>check one</i> )		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1. 09/393,456	September 10, 1999			
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No fee is owed by the applicant(s).
- ☐ The IDS Fee of \$180 under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$ .
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$ . (A duplicate copy of this communication is enclosed for that purpose.)


**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of ALAM et al.  
Application No. 10/034,432

**Instructions as to Overpayment**

☒ Credit Account No. 12-1216.  
☐ Refund

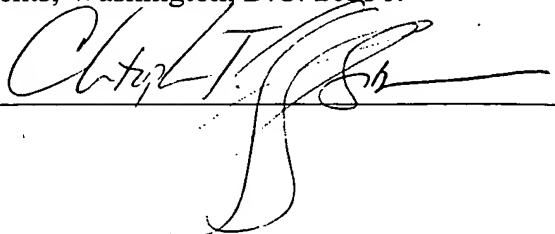
  
\_\_\_\_\_  
Christopher T. Griffith, Reg. No. 33,392  
LEYDIG, VOIT & MAYER, LTD.  
Two Prudential Plaza, Suite 4900  
180 North Stetson  
Chicago, Illinois 60601-6780  
(312) 616-5600 (telephone)  
(312) 616-5700 (facsimile)

Date: March 20, 2002

**CERTIFICATE OF MAILING**

I hereby certify that this INFORMATION DISCLOSURE STATEMENT (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

Date: MARCH 20, 2002

  
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IDS (Rev. 2/27/2002)

FORM PTO-1449  
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201684SERIAL NO.  
09/393,456INFORMATION DISCLOSURE STATEMENT  
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Flower et al.FILING DATE  
September 10, 1999GROUP  
3736

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	1,048,419	03/65	Krumbiegel et al.			
	AB	2,895,955	07/59	Heseltine et al.			
	AC	3,736,524	05/73	Drexhage			
	AD	3,893,447	07/75	Hochheimer et al.			
	AE	4,369,250	01/83	Gindler			
	AF	4,412,543	11/83	Vassiliadis et al.			
	AG	4,466,442	08/84	Hilmann et al.			
	AH	4,541,438	09/85	Parker et al.			
	AI	4,573,778	03/86	Shapiro			
	AJ	4,608,990	09/86	Elings			
	AK	4,762,701	08/88	Horan et al.			
	AL	4,786,813	11/88	Svanberg et al.			
	AM	4,799,783	01/89	Takahashi et al.			
	AN	4,821,117	04/89	Sekiguchi			
	AO	4,835,103	05/89	Cercek et al.			
	AP	4,842,401	06/89	Maurice			
	AQ	4,859,584	09/89	Horan et al.			
	AR	5,092,331	03/92	Nakamura et al.			
	AS	5,126,235	06/92	Hioki			
	AT	5,141,303	08/92	Yamamoto et al.			
	AU	5,150,292	09/92	Hoffmann et al.			
	AV	5,163,437	11/92	Fujii et al.			
	AW	5,225,859	07/93	Fleischman			
	AX	5,247,318	09/93	Suzuki			
	AY	5,277,913	01/94	Thompson et al.			
	AZ	5,279,298	01/94	Flower			
	BA	5,292,362	03/94	Bass et al.			
	BB	5,303,709	04/94	Dreher et al.			
	BC	5,315,998	05/94	Tachibana et al.			
	BD	5,394,199	02/95	Flower			
	BE	5,400,791	03/95	Schlier et al.			
	BF	5,438,989	08/95	Haglund et al.			
	BG	5,441,858	08/95	Delprato et al.			
	BH	5,450,144	09/95	Ben Nun			
	BI	5,552,452	09/96	Khadem et al.			
	BJ	5,569,587	10/96	Waggoner et al.			
	BK	5,573,750	11/96	Singh			

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	BL	5,576,013	11/96	Williams et al.			
	BM	5,618,733	04/97	Sakata et al.			
	BN	5,624,597	04/97	Buhl et al.			
	BO	5,643,356	07/97	Nohr et al.			
	BP	5,648,062	07/97	Klaveness et al.			
	BQ	5,676,928	10/97	Klaveness et al.			
	BR	5,691,204	11/97	Kantor et al.			
	BS	5,707,608	01/98	Liu			
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	BU	5,716,642	02/98	Bagchi et al.			
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	BW	5,747,475	05/98	Nordquist et al.			
	BX	5,750,722	05/98	Huynh et al.			
	BY	5,762,957	06/98	Mehlhorn			
	BZ	5,773,299	05/98	Kim et al.			
	CA	5,804,448	09/98	Wang et al.			

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		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO*
	CB	1048419		Great Britain				
	CD	244492	04/87	Germany (East)			Abs only	
	CE	87042892	09/87	Japan			Abs only	
	CF	3926652	04/91	Germany			Abs only	
	CG	96/31237	12/96	WIPO				
	CH	97/31582	09/97	WIPO				
	CI	97/33620	09/97	WIPO				
	CJ	589825	05/98	Europe				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	CK	"Photosensitizer," <i>Ophthalmic Surgery and Lasers</i> , Vol. 28, No. 5, p 410 (1997).
	CL	Desmettre et al., "Diode Laser-Induced Thermal Damage Evaluation on the Retina with a Liposome Dye System," <i>Lasers in Surgery and Medicine</i> , Vol. 24, pp. 61-68 (1999).
	CM	Flower et al., "Evolution of Indocyanine Green Dye Choroidal Angiography," <i>Optical Engineering</i> , Vol. 34, No. 3, pp. 727-736 (1995).
	CN	Flower et al., "Pulsatile Flow in the Choroidal Circulation: A Preliminary Investigation," <i>EYE</i> , Vol. 4, pp. 310-318 (1990).
	CO	Flower et al., "Variability in Choriocapillaris Blood Flow Distribution," <i>Investigative Ophthalmology &amp; Visual Science</i> , vol. 36, No. 7, pp. 1247-1258 (1995).
	CP	Flower, "Choroidal Angiography Today and Tomorrow," <i>Retina</i> , Vol. 12, No. 3, pp. 189-190 (1992).

FORM PTO-1449  
(Rev. 2-32)

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CQ	Flower, "Extraction of Choriocapillaris Hemodynamic Data from ICG Fluorescence Angiograms," <i>Investigative Ophthalmology &amp; Visual Science</i> , Vol. 34, No. 9, pp. 2720-2729 (1993).
CR	Flower, "Injection Technique for Indocyanine Green and Sodium Fluorescein Dye Angiography of the Eye," <i>Investigative Ophthalmology</i> , Vol. 12, No. 12, pp. 881-895 (1973).
CS	Gathje et al., "Stability Studies on Indocyanine Green Dye," <i>Journal of Applied Physiology</i> , Vol. 29, No. 2, pp. 181-185 (1970).
CT	Holzer et al., "Photostability and Thermal Stability of Indocyanine Green," <i>J. Photochem. Photobiol. B: Biol.</i> Vol. 47, pp. 155-164 (1998).
CU	Klein et al., "An Image Processing Approach to Characterizing Choroidal Blood Flow," <i>Investigative Ophthalmology &amp; Visual Science</i> , Vol. 31, No. 4, pp. 629-637 (1990).
CV	Miki et al., "Computer Assisted Image Analysis Using the Subtraction Method in Indocyanine Green Angiography," <i>European Journal of Ophthalmology</i> , Vol. 6, No. 1, pp. 30-38 (1996).
CW	DuBosar, "Population at Risk: Age-Related Macular Degeneration," <i>Ocular Surgery News</i> , 10 Pages, (May 15, 1998).
CX	Chen et al., "Photothermal Effects on Murine Mammary Tumors Using Indocyanine Green and an 808-nm Diode Laser: an in vivo Efficacy Study," <i>Cancer Lett.</i> , Vol. 98, No. 2, pp. 169-173 (1996).
CY	Alcon Pharmaceuticals Ltd. "Pharmacocyclics Inc," <i>The Business and Medicine Report</i> , p. 63 (January 1998).
CZ	Shiraga et al., "Feeder Vessel Photocoagulation of Subfoveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration," <i>Ophthalmology</i> , Vol. 105, No. 4, pp. 662-669 (1998).

EXAMINER

DATE CONSIDERED

\*A concise statement of relevance is being submitted in lieu of a translation. 37 CFR §1.98(b).  
1449FORM (Rev. 7/15/1999)

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## U.S. PATENT DOCUMENTS

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	DA	3,871,772	03/75	Munnerlyn et al.			
	DB	3,944,341	03/76	Pomerantzeff			
	DC	4,056,310	11/77	Shimizu et al.			
	DD	4,251,139	02/81	Matsumura			
	DE	4,978,213	12/90	El Hage			
	DF	5,072,731	12/91	Taratuta et al.			
	DG	5,116,114	05/92	Nakamura			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO*
	DH	2034916	06/80	Great Britain				
	DI	3124305	01/83	Germany			Abs only	
	DJ	0109846	05/84	Europe				
	DK	0554643	08/93	Europe				
	DL	0649667	04/95	Europe				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)


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DM	Flower et al., "Clinical Infrared Absorption Angiography of the Choroid," <i>American Journal of Ophthalmology</i> , Vol. 73, No. 3, pp. 458-459 (1972)
DN	Flower et al., "A Clinical Technique and Apparatus for Simultaneous Angiography of the Separate Retinal and Choroidal Circulations," <i>Investigative Ophthalmology</i> , Vol. 12(4), pp. 248-261 (1973)
DO	Hochheimer et al., "Angiography of the Cervix," <i>Johns Hopkins Medical Journal</i> , Vol. 135, pp. 375-382 (1974)
DP	Flower, "High Speed Human Choroidal Angiography Using Indocyanine Green Dye and a Continuous Light Source," <i>International Symposium on Fluorescein Angiography, Documenta Ophthalmologica Proceedings Series</i> , Vol. 9, pp. 59-64 (1976)
DQ	Flower et al., "Indocyanine Green Dye Fluorescence and Infrared Absorption Choroidal Angiography Performed Simultaneously with Fluorescein Angiography," <i>Johns Hopkins Medical Journal</i> , Vol. 138, No. 2 pp. 33-42 (1976)
DR	Orth et al., "Potential Clinical Applications of Indocyanine Green Choroidal Angiography," <i>The Eye, Ear, Nose and Throat Monthly</i> , Vol. 55, January, pp. 15-28, 58 (1976)
DS	Patz et al., "Clinical Applications of Indocyanine Green Angiography," <i>International Symposium on Fluorescein Angiography, Documenta Ophthalmologica</i> , Vol. 9, pp. 245-251 (1976)
DT	Flower, "Choroidal Fluorescent Dye Filling Patterns a Comparison of High Speed Indocyanine Green and Fluorescein Angiograms," <i>International Ophthalmology</i> , Vol. 2(3), pp. 143-150 (1980)
DU	Hyvarinen et al., "Indocyanine Green Fluorescence Angiography," <i>ACTA Ophthalmologica</i> , Vol. 58, pp. 528-538 (1980)
DV	Bischoff et al., "Ten Years Experience with Choroidal Angiography Using Indocyanine Green Dye-A New Routine Examination or an Epilogue," <i>Doc Ophthalmology</i> , Vol. 60(3), pp. 235-291 (1985)
DW	Murphy et al., "Effects of Retinal Photocoagulation on the Choroidal Circulation," <i>Investigative Ophthalmology &amp; Visual Science</i> , Vol. 32(4), p. 785 (1991) MEETING ABSTRACT
DX	Murphy et al., "Indocyanine Green Angiographic Studies of Occult Choroidal Neovascularization," <i>Investigative Ophthalmology &amp; Visual Science</i> , Vol. 34(4), p. 1134 (1993) MEETING ABSTRACT
DY	Flower, "Binding and Extravasation of Indocyanine Green Dye," <i>Retina</i> , Vol. 14, No. 13, pp. 283-284 (1994)
DZ	Lim et al., "Indocyanine Green Angiography," <i>International Ophthalmology Clinics</i> , Vol. 35(4), pp. 59-70 (1995)
EA	Hiner et al., "A Previously Undescribed Indocyanine Green Angiographic Filling Pattern," <i>Investigative Ophthalmology &amp; Visual Science</i> , Vol. 36, No. 4 (1995) Summary MEETING ABSTRACT
EB	Flower et al., "Disparity Between Fundus Camera and Scanning Laser Ophthalmoscope Indocyanine Green Imaging of Retinal Pigment Epithelium Detachments," <i>Retina</i> , Vol. 18(3), pp. 260-268 (1998)
EC	Staurenghi et al., "Laser Treatment of Feeder Vessels in Subfoveal Choroidal Neovascular Membranes," <i>Ophthalmology</i> , Vol. 105, No. 12, pp. 2297-2305 (1998)
ED	Flower et al., "Expanded Hypothesis on the Mechanism of Photodynamic Therapy Action on Choroidal Neovascularization," <i>Retina</i> , Vol. 19, No. 5 pp. 365-369 (1999)
EE	Flower, "Experimental Studies of Indocyanine Green Dye-Enhanced Photocoagulation of Choroidal Neovascularization Feeder Vessels," <i>American Journal of Ophthalmology</i> Vol. 129, No. 4, pp. 501-512 (2000)

EXAMINER

DATE CONSIDERED

FORM PTO-1449  
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U.S. DEPARTMENT OF COMMERCE  
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ATTY. DOCKET NO.  
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## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	EK	Mendelson et al., "Amelioration of Experimental Lipid Keratopathy by Photochemically Induced Thrombosis of Feeder Vessels," <i>Arch Ophthalmol</i> , Vol. 105, July 1987 (pp. 983-988).
	EL	Tsilimbaris et al., "Photothrombosis Using Two Different Phthalocyanine Administration Routes: Continuous I.V. Infusion v. Bolus I.V. Injection," <i>Photochem. Photobiol.</i> , 62(3), 1995, (pp. 435-441).
	EM	Spinelli et al., "Endoscopic Treatment of Gastrointestinal Tumors: Indications and Results of Laser Photocoagulation and Photodynamic Therapy," <i>Seminars in Surgical Oncology</i> , 11 (4), 1995, (pp. 307-18) (Abstract only)
	EN	Von Kerczek et al., "The Effects of Indocyanine Green Dye-Enhanced Photocoagulation on the Blood Flow in the Choriocapillaris and the Choroidal Neovascularization," <i>Advances in Heat and Mass Transfer in Biotechnology</i> , 2000, (pp. 1-3). (Abstract only).

EXAMINER

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\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).